

OPERATORS GUIDE

Rocket CRAFT™

Oocyte Aspiration Pumps



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2. GENERAL ASSEMBLY

2.1. Rocket CRAFT™ DUO-VAC Suction Pump



1. Illuminated O/I Mains Power On/Off
2. Vacuum Control Dial – clockwise to increase, anticlockwise to decrease the set value
3. Vacuum Display mmHg⁻¹
4. Footswitch connection ports
5. Water trap connection port – recommended for use with R57685 Rocket Craft Pump Water Trap Sets
6. Water Trap Set comprising glass bottle, bung, angled connectors, silicone tube set. Recommended for use with R57685 Rocket Craft Pump Water Trap Sets
7. Silicone tube set with metal luer connector
8. Medium Vacuum (Standard) 50-250mmHg⁻¹ & High Vacuum 440mmHg⁻¹ foot-switch

2.2.Rocket CRAFT™ Suction Pump



Rocket Craft Suction Pump with earlier metal footswitch.

1. Illuminated O/I Mains Power On/Off
2. Vacuum Display mmHg⁻¹
3. High Vacuum (440mmHg-1) control button
4. Vacuum Control – clockwise to increase, anticlockwise to decrease the set value
5. Water trap connection port – recommended for use with R57685 Rocket Craft Pump Water Trap Sets
6. Water Trap Set comprising glass bottle, bung, angled connectors, silicone tube set.
7. Footswitch connection port
8. Medium Vacuum (Standard) 50-250mmHg⁻¹ footswitch
9. Silicone tube set with metal luer connector



Footswitch supplied on Rocket Craft Suction Pumps 2013 onwards



WARNING:
READ THIS MANUAL CAREFULLY: Please familiarise yourself with the contents of this manual before attempting to use the device.

Failure to observe these instructions may result in damage to the pump or cause injury to the patient or user.

This device should only be used by suitably qualified personnel.



WARNING:
ELECTRIC SHOCK HAZARD.

The equipment is to be used only with electrical systems complying with all IEC, CEC and NEC requirements.



CAUTION:
Any adjustment, modification or repairs to the equipment should be carried out by authorised service agents.



Disposal of this device must be undertaken with regard to the WEEE directive (2002/96/EC).

3. GENERAL INSTRUCTIONS

3.1. COPYRIGHT

This manual contains information that is subject to copyright. All rights reserved. This manual should not be photocopied, duplicated or distributed completely or in part without the approval of Rocket Medical plc.

3.2.MODEL NUMBERS:

Rocket Craft™ Suction Pump Complete (110v)	R29654
Rocket Craft™ Suction Pump Complete (240v)	R29655
Rocket Craft™ Duo Vac™ Suction Pump (240v)	R29660
Rocket Craft™ Duo Vac™ Suction Pump (110v)	R29661

3.3. MANUAL REVISION:

Revision 8:	New specification based on Rev 7	25/05/10
Revision 9:	Updated CSD address graphics	07/06/10
Revision 10	Symbol tables & storage/transport	28/10/11
Revision 11	CE Mark, manufacturer data	21/11/11
Revision 12	Update to consumables info, voltage	01/12/11
Revision 13	Terminology change Low-Medium	05/12/11
Revision 14	Amend voltage statement in Section 4	07/12/11
Revision 15	CE mark amendment	07/12/11
Revision 16	Symbol correction	30/05/12
Revision 17	Correction to annotated images	29/06/12
Revision 18	Update images with new footswitch	30/09/13
Revision 19	Update to latex statement and symbol	06/11/13
Revision 20	Image to clarify footswitch controls	14/11/13
Revision 21	Amend EMC revision	15/04/14
Revision 22	Update to: YOM, consumption, footer	16/07/14
Revision 23	Update to LRQA CE mark	27/08/14
Revision 24	Gauge images, water trap cleaning ins.	17/12/14

3.4. MANUFACTURER:

	Rocket Medical plc Sedling Road WASHINGTON Tyne & Wear NE38 9BZUK.	
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3.5. SERVICE AGENTS:

Rocket Craft™ Pumps typically require little routine maintenance; however they must be serviced and calibrated annually at a **Rocket Medical plc** service facility.

Failure to service the pump at the indicated intervals may invalidate the Warranty.

Customer Services:

Rocket Medical plc. Sedling Road. WASHINGTON. NE38 9BZ. ENGLAND
Tel: +44 (0) 191 419 6988. Fax: +44 (0) 191 419 6989
Email: homesales@rocketmedical.com

US Office:

Rocket Medical. Unit 1. 150 Recreation Park Drive
HINGHAM. MA 02043. USA
Tel: 1 781 749 6223. Fax: 1 781 749 6235
Email: usa@rocketmedical.com



WARNING:

This manual contains important information. Please familiarise yourself with these safety instructions before using the device.



WARNING:

This device should only be operated by appropriately qualified personnel.



WARNING:

This device must only be operated with approved consumables.



WARNING:

Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent



WARNING:

Ensure the set vacuum level is appropriate.



WARNING:

No user serviceable parts inside.



WARNING:

Device can cause explosion in the presence of flammable gases.

4. SAFETY INSTRUCTIONS

This manual describes the operation and intended use of the device and the associated consumables and it is essential that you use this document to familiarise yourself with the correct function and operation of the device before use.

Failure to follow these instructions may result in serious injury to the patient or operator and can lead to damage or breakdown of the device. In case the device fails during an operation, a replacement device and replacement disposables should be kept within reach so that the operation may be completed.

This manual does not provide a detailed description of the oocyte harvesting procedure and is not intended as a training guide for users inexperienced in the technique.

The device must only be used with R57685 Rocket CRAFT™ Water Trap (Patient Connection) Sets or the water trap set supplied with the pump. The usage of non-approved tubing or filter sets may impair pump performance, lead to increased risk to patients and harvested oocytes and will invalidate the Warranty.

The water trap sets are designed to prevent fluid contamination of the vacuum pump. If the device has been used with a non-approved filter set or there is any evidence or suspicion that the pump may have been contaminated with fluid during use, it must be removed from service and returned for examination immediately. Please contact your nearest Service Centre for advice.

The use of high vacuum levels may lead excessive fluid *flow rates* which may result in damage to the oocyte and reduced fertilisation rates. Damage to oocytes in harvesting systems is principally caused by *turbulent flow* which can lead to physical shearing stresses on the cumulus sufficient to denude or damage the fragile zona (Reeves et al 1989). Flow rate is a function needle set configuration and vacuum applied.

HIGH vacuum setting must *only* be used to clear blockages from a needle set.

Refer to Table 1 for recommended vacuum setting for given needle set configurations.

Refer all servicing to the manufacturer's authorised service agent.

Do not use in an area where flammable gases are present.



**WARNING:
ELECTRIC SHOCK
HAZARD.**

The equipment is to be used only with electrical systems complying with all IEC, CEC and NEC requirements.



**WARNING:
ELECTRIC SHOCK
HAZARD.**

Do not immerse the device.



WARNING:
Device can cause explosion in the presence of flammable gases.

4.1. SUPPLY VOLTAGE SELECTION

The device operates at a voltage 220-240 VAC @ 50Hz. 0.12A or 110VAC @ 60Hz as appropriate to the model.

Ensure that the correct power cord is connected.

4.2.ELECTROMAGNETIC COMPATIBILITY

Rocket CRAFT™ Oocyte Aspiration Pumps comply with the electromagnetic compatibility (EMC) limits for medical devices as specified by IEC 60601-1:1990.

The device must be operated according to the instructions contained in this manual to ensure continued electromagnetic compatibility.

4.3.PACKAGING

The packaging has been designed to allow secure transportation of the pump and its accessories.

After unpacking, re-assemble and retain the packaging for transport for servicing when required.

4.4. POSITIONING and PLACEMENT of the DEVICE

Rocket CRAFT™ Oocyte Aspiration Pumps must be placed on a secure, level surface, away from sources of heat, water splashes, mists or cooling vents. Do not expose to direct sunlight.

Do not expose to flammable gases.

Operating temperature Range: +5°C and +35°C

4.5. SYMBOLS USED ON CRAFT SUCTION & DUO-VAC PUMPS.

These tables describe their respective meanings.

	Mains Power ON/OFF
	This device is Type B
	CE Mark

4.6. SYMBOLS USED ON R57685 – PATIENT CONNECTION SET.

	Read the Instruction for Use before connection and use
	Device is for Single Use Only
	Device is sterilised by Ethylene Oxide
	The device is Latex Free
	CE Mark

5. GENERAL INFORMATION:

5.1. GENERAL DESCRIPTION:

The Rocket CRAFT™ Oocyte Aspiration Pumps have been developed to provide smooth, low volume vacuum at a pre-determined negative pressure. Vacuum is activated by a foot operated toggle air switch controlled by the surgeon performing the oocyte collection.

The range of vacuum is infinitely variable from 10-250mmHg⁻¹ in medium vacuum mode and at a pre-set 440mmHg-1 in high vacuum mode.

Rocket CRAFT™ Oocyte Aspiration Pumps require either a water trap set (supplied) or R57685 Disposable Rocket CRAFT™ Water Trap Sets, supplied separately, sterile and for single patient use.

A suitable collection test tube for use with oocyte needle sets is B.D. Falcon test tube No. 2001F, 17 x 100mm.

5.2. INDICATIONS:

For the generation of medium vacuum between 10-250 mmHg⁻¹ to permit the aspiration of follicular fluid, oocytes and ovarian fluid as part of the treatment of infertility relating to IVF and other gynaecological procedures.

This device may only be used by, or under the supervision of, appropriately trained personnel in conjunction with clinical practice guidelines such as those published by the National Institute of Clinical Excellence (NICE 2004) and the Human Fertilisation & Embryology Authority. (HFEA April 2010 – as amended).

5.3. CONTRAINDICATIONS:

Not intended for use where ovarian aspiration or the aspiration of ovarian fluid is contraindicated. For short term operation only. NOT for continuous drainage.

5.4. REFERENCES:

Craft I, McLeod F. Edmonds K, 'Human embryo transfer technique'. Lancet 1961 ii 1104-5
Craft I, Diahnbakch O. McLeod F et al 'Human pregnancy following oocyte and sperm transfer to the uterus.' Lancet 1992 i 1031-3
Craft I, (1984) 'Clinical Methodology' British Journal of Hospital Medicine 90-102
Reeves G, Scott R T, et al (1989) Journal of Assisted Reproduction and Genetics Volume 6, Number 6 / December, 1989



WARNING:

This device must only be operated with approved consumables.



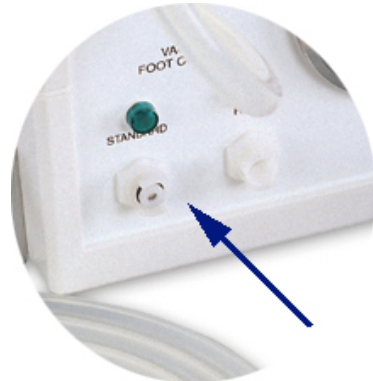
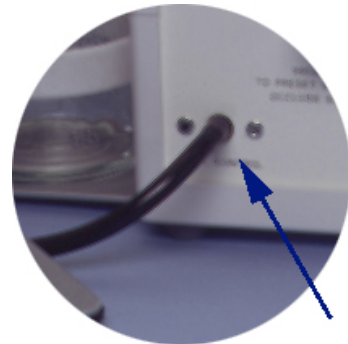
WARNING:

Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent

6. OPERATING THE PUMP

Rocket CRAFT™ Suction Pump:

1. Unwrap the footswitch and attach the air tubing to the ports on the front of the pump casing. The footswitch is normally left attached to unit in daily use unless removal for storage is required.



Rocket CRAFT™ Suction Pump:

2. Unwrap the footswitch and attach the air tubing to the male/female ports on the front of the pump casing. The footswitch is normally left attached to unit in daily use unless removal for storage is required.





WARNING:
ELECTRIC SHOCK
HAZARD.

The equipment is to be used only with electrical systems complying with all IEC, CEC and NEC requirements.

1. Connect the correct mains lead to an electrical supply 110-240VAC 50-60Hz. Model dependant
2. Turn the power switch 0-I (front panel) to on. The green light illuminate.



3. Connect the short limb of the water trap set to the port (indicated)

or:

4. Using aseptic technique, un-pack the R57685 Rocket CRAFT™ Water Trap Set and attach the short tubing length to the spigot (indicated).
5. Pass the longer patient connection tube into the operative field. The R57685 water trap set is for single patient use and must be replaced for each patient.



6. Refer to Table 1 for recommend vacuum values for various needle and tube set combinations

7. Occlude the patient tube set, distal to the water trap.

8. Activate the foot switch

9. Rotate the control knob *clockwise* to increase to the desired value on the gauge

10. To decrease the set value: rotate anticlockwise.

11. When the desired value is reached, release the footswitch and tubing set occlusion.

12. Repeat from Step 8 to ensure stable value.



WARNING:
Ensure the set vacuum level is appropriate to the patient's needs taking into consideration the needle and tube set configuration



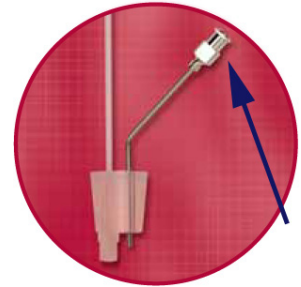
WARNING:

Ensure the set vacuum level is appropriate to the patient's needs taking into consideration the needle and tube set configuration

6.1. TABLE 1 RECOMMENDED VACUUM SETTINGS

	Single Lumen		Double Lumen	
	16G	17G	16G	17G
Tube Set Length	Recommended Vacuum -mmHg			
55cm	80	110	130	150
70cm	90	130	150	170
90cm	100	150	170	190

13. Connect the patient filter set to a suitable luer fitting (indicated) such as that found on the Rocket Oxford Tube Set found on Rocket Single and Double Lumen Oocyte Aspiration Needles and attach a collection tube to the bung.



If vacuum lines become blocked due to debris or viscous fluids, a temporary high vacuum (440mmHg-1) can be obtained to unblock the needle and tubing set by following the procedures below



WARNING:

HIGH VACUUM MODE must NOT be used to aspirate oocytes as this may result in damage to the oocyte and lead to reduced fertilisation rates.

Rocket CRAFT™ DUO-VAC

14. To activate the HIGH vacuum, depress the WHITE HIGH VACUUM Pedal – the pump will immediately deliver a vacuum of 440mmHg-1.



Rocket CRAFT™ Suction Pump

15. To activate the HIGH vacuum, occlude the RED button and depress the footswitch – the pump will immediately deliver a vacuum of 440mmHg⁻¹.
16. Removing the occlusion will cause the vacuum to revert to its previously set level.





WARNING:

This device must only be operated with approved consumables which are specifically designed to provide the correct flow rates and vacuum characteristics

Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent

1. If water, media or any other material is allowed to enter the water trap chamber, the pump must be stopped **immediately**.
2. Remove the water trap from the device, empty any fluid. Decontaminate the water trap if required following local hospital guidelines and refit before use.
3. The pump must NOT be operated if fluid is present in the water trap.
4. Should the water trap become full and there is a risk that fluid has entered the pump, it must be withdrawn from service and returned to an authorised service agent for inspection and repair.



6.2. CLEANING & STERILISING THE REUSABLE WATER TRAP

This device should be cleaned in accordance with local hospital policy and with regard to all applicable regulations, including but without limitation to, those pertaining to human health & safety and care of the environment such as those published by the Institute of Decontamination Sciences (Standards and Practice 3rd ed. (as amended)).

1. Remove the water trap bottle and tubing from the pump
2. Separate the tubing and bung set ❷ from the glass bottle❸. The silicone tubing does not need to be detached from the bung set unless it has been contaminated in use.
3. Wash the tubing and bung set and bottle under warm running water. Very hot water will cause coagulation of proteinous substances and should not be used. Mechanical washing machines and ultrasonic cleaners, using instrument detergents of strength recommended by the manufacturer may be used followed by a clean rinse.
4. Neutral (ph7) detergents should be used during manual, mechanical or ultrasonic cleaning. The concentration and volume of detergents used should be in line with the detergent manufacturer's instructions.
5. Immediately after washing, the bottle and tubing and bung set should be dried completely either by hand or in a suitable warm air cabinet
6. The bung/tubing set and bottle should be packed separately in autoclavable pouches. Do not sterilise assembled.
7. The recommended method for sterilisation is steam sterilisation @ 134°C (+3°C – 0°C) for minimum of 3 minutes.

This recommendation should be used in conjunction with the standards and guidelines laid down in ISO 17665-1:2006: Sterilization of health care products - Moist heat. Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices and ISO/TS 17665-2:2009 Sterilization of health care products: Moist heat - Part 2: Guidance on the application of ISO 17665-1





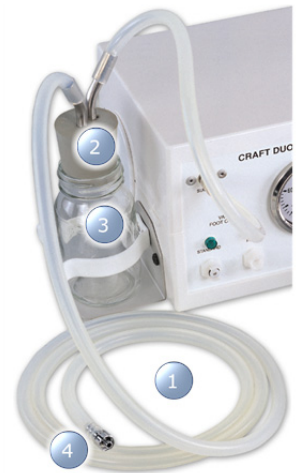
WARNING:

This device must only be operated with approved consumables which are specifically designed to provide the correct flow rates and vacuum characteristics

Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent

7. CONSUMABLES

1. The following items should be replaced annually, earlier if subjected to repeated autoclaving and showing signs of wear or poor sealing qualities.
 - a. R28406: Water trap bottle & bung set ② ③
 - b. R28135: Silicone tubing including metal luer fitting ① ④



2. For users who prefer not to reprocess the water trap, a sterile single patient use option is available and replaces the non-sterile bottle set which is supplied with the pump.

R57685 Rocket CRAFT™ Water Trap (Patient Connection) Set

glass water trap bottle 2.5m patient connection tube with male luer connector. Supplied sterile, for single use in cartons 10 units.





WARNING:
ELECTRIC SHOCK
HAZARD.

Do not immerse the device.



WARNING:
Do NOT attempt to
sterilise the device



WARNING:
Protect the device from
ingress of liquid. Should
any liquid enter the
device, discontinue use
immediately and refer
to an authorised service
agent



WARNING:
No user serviceable
parts inside.



HAZARD:
Do NOT include used
consumables as these
pose a significant
contamination risk



IMPORTANT

A decontamination
certificate MUST be
included with every
returned pump.

Repair or servicing
cannot be commenced
unless the service
agent is in possession
of this certificate

8. CLEANING THE PUMP CASING

At the end of each clinical session, turn off the device at the front panel and disconnect the device from mains power supply

Using an aqueous solution of 70% alcohol (IMS or isopropyl BP), moisten a cloth and wipe all external surfaces of the device. If the surface has become contaminated with proteinaceous material, remove with a light detergent solution before surfacing cleaning with alcohol.

Do NOT use a 100% alcohol or any other solvent to clean the device as this may cause damage to the casing surface and display.

Prevent any fluid from entering the device.

9. YEAR OF MANUFACTURE:



Units manufactured before 2014: The year in which the device was manufactured is indicated by the first 2 numbers of the serial number. For example: a serial number starting **11**180776 indicates the device was manufactured in 2011

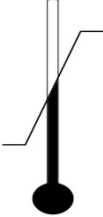
For units manufactured after 01/04/14, the year of manufacture is shown on the rear rating plate label opposite the model number.

10. RETURNING THE PUMP FOR SERVICE:

All devices to be returned must be prepared as described below for the protection of the servicing team and for safety during transport.

1. Surface clean the pump as described in the Section above
2. Seal in a plastic bag and seal within a second plastic bag.
3. Place in the original packaging.
4. Enclose the following information:
 - Contact name
 - Centre address
 - **Decontamination Certificate**
 - Description of the fault or service required
 - Accompanying Order to authorise servicing – contact your local Customer Services Team for details

11. STORAGE:

	The device must be stored and operated in temperatures +5°C to +35°C
	The device must be stored in a clean, dry condition, ideally in its original packaging which should be retained to return the unit for servicing Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent

12. TRANSPORTATION:

	The device must be transported in temperatures +5°C to +35°C	
	The device is FRAGILE and must be transported in its original packaging to ensure protection. If the original packaging is not available please contact your local Customer Services Agent who will provide replacement packaging.	
	Dimensions: • W - 264mm • H - 124mm • D - 164mm	Weight: • Unit – 1.9Kg • Foot Switch: ○ 0.57Kg – DUOVAC (plastic) ○ 0.34kg – Craft Suction (plastic) ○ 0.51Kg – DUOVAC (metal) ○ 0.38kg – Craft Suction (metal)
	Protect the device from ingress of liquid. Should any liquid enter the device, discontinue use immediately and refer to an authorised service agent	

13. WARRANTY

Rocket CRAFT™ Oocyte Aspiration Pumps are sold by **Rocket Medical plc** under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of the Products directly from **Rocket Medical plc** as new merchandise and are extended to the first Buyer thereof, other than for resale.

For a period of twelve (12) months from the date of shipment the Products are warranted to be free from functional defects in materials and workmanship and to conform to the description of the Products contained in the operating manual and accompanying labels, provided the same is properly operated under conditions of normal use, that annual maintenance and service is performed at an authorised **Rocket Medical plc** service facility

Removal of any QC seal voids the warranty.

The foregoing warranties shall not apply if the Products have been repaired other than by **Rocket Medical plc** or other than in accordance with written instructions provided by **Rocket Medical plc**, or altered by anyone other than **Rocket Medical plc**, or if the Products have been subject to misuse, negligence, or accident.

Rocket Medical plc's sole and exclusive obligation and Buyer's sole and exclusive remedy under the above warranties is limited to repairing or replacing, free of charge, at **Rocket Medical plc**'s option, Products, which are reported to **Rocket Medical plc** by mail, telephone or email and which, if so advised by **Rocket Medical plc**, is thereafter returned with a statement of the observed deficiency, not later than seven (7) days after the expiration date of the warranty, to **Rocket Medical plc** during normal business address, transport charges prepaid and which, upon **Rocket Medical plc**'s examination, is not found to conform with the above warranties.

Rocket Medical plc shall not be otherwise liable for any damages including but not limited to incidental damages, consequential damages or special damages.

There are no express or implied warranties which extend beyond the warranties herein above set forth. **Rocket Medical plc** makes no warranty of merchantability or fitness for a particular purpose with respect to the Products or parts thereof.

14. TECHNICAL SPECIFICATIONS

14.1.CLASSIFICATION

IEC 60601-1

Degree of protection against electric shock: Type B

14.2. SPECIFICATIONS

Power Input to Pump: 220-240 VAC @ 50Hz. 0.12A

Maximum current: 2.5A

Consumption: 0.6KW/h

Environmental conditions:

- Temperature +5°C to +35°C
- Atmospheric Pressure Range: 700-1060hPA

Dimensions:

- W - 264mm
- H - 124mm
- D - 164mm

Weight:

- Unit – 1.9Kg
- Foot Switch 0.51Kg

Vacuum Ranges:

- Medium vacuum: -20mmHg to -250mmHg in 20mmHg increments
- High vacuum: -440mmHg

Vacuum Range Accuracy: ±10%